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Boston Scientific

CLINICIAN USER MANUAL

LATITUDE Consult™ System

CAUTION:
Federal (USA) law restricts this device to distribution and use by or on the lawful order of a physician.

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INTRODUCTION

The LATITUDE Consult™ system provides clinicians a convenient and secure way to review data from a Boston Scientific implanted device.

Intended Use

The LATITUDE Consult system is intended to read data from a compatible Boston Scientific implanted device and transfer it to a central server. The LATITUDE Consult system can provide implanted device data that may be used as part of the clinical evaluation of the patient.

This literature is intended for use by health care providers of the LATITUDE Consult Communicator System.

How the System Works

The LATITUDE Consult Communicator is used to read data from a patient's implanted device via a telemetry wand placed over the patient's device. Once the data is read, the clinician uses the Communicator to send the data to the secure LATITUDE Consult server. The clinician then contacts Boston Scientific to request a review of the data and optionally obtain reports. This data will also be made available and can be viewed within the LATITUDE NXT system by any clinic that has enrolled the patient.

Contraindications

The LATITUDE Consult Communicator is contraindicated for use with any implanted device other than a compatible Boston Scientific implanted device. Not all Boston Scientific implanted devices are compatible with the LATITUDE Consult system. For contraindications for use related to the implanted device, refer to the System Guide for the Boston Scientific implanted device being read.

Warnings

The Communicator is MR (Magnetic Resonance) Unsafe. The Communicator is MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices[1]. Under no circumstances should the Communicator be brought into the MRI scanner room, the control room, or the MRI site Zone III or IV areas.

LATITUDE Consult is a trademark of Boston Scientific or its affiliates.

1. American College of Radiology (ACR), AJR June 2007;188:1-27

Precautions

In order to ensure a review by Boston Scientific of the patient's implanted device data, the clinician must call LATITUDE Consult Technical Services at 1-800-CARDIAC (227-3422) after sending the data.

Adverse Effects

None known.

System Limitations

This system is intended for use by health care providers in a health care facility. As appropriate, clinical care needs to be provided to the patient, separate from the use of the Communicator.

The LATITUDE Consult system can only read data from an implanted device and cannot reprogram, command lead tests, or change any functions of the implanted device. Therefore, LATITUDE Consult Communicator interrogations are not intended to be used in place of in-office follow ups that involve programming of the implanted device (e.g., changing device settings) or commanding lead tests (e.g., pacing threshold test). The implanted device can only be programmed with a Programmer/Recorder/Monitor (PRM).

There are many internal and external factors that can hinder, delay, or prevent reading and sending implanted device information. These factors include:

- Health Care environment.
  - Delays in contacting clinicians may occur for a variety of reasons including fax and computer equipment that may be down or offline, and the unavailability of health care staff.
  - To read or send implanted device data, the LATITUDE Communicator must be plugged into an electrical outlet.
  - The LATITUDE Communicator needs an analog telephone line **OR** an Internet connection to send (transmit) data to the remote, secure server. See "LATITUDE Consult Communicator" on page 5.
- Analog telephone connection. Variations in infrastructure compatibility among telephone service providers as well as variations in the quality of the telephone line from the health care facility to the telephone company equipment and switching stations can affect sending the LATITUDE Consult Communicator implanted device data.

- Internet connection. Work with your System Administrator to ensure the LATITUDE Consult Communicator system is approved for use in your network environment.
    - If the LATITUDE Communicator is using an Internet connection, the Communicator should be located within 100 feet (30 meters) of the LATITUDE Wireless Internet Adapter.
    - If a server call fails, ensure the TCP/UDP port 443 is not blocked by your network. In addition, access to DNS traffic to/from IP address 165.87.13.129 and 165.87.201.244 must be permitted.
- Equipment. Reading or sending implanted data can be prevented due to:
    - The implanted device cannot establish and complete a telemetry (reading implanted device data) session
    - The Communicator is damaged or malfunctions
- Data processing. Sending implanted device data can be delayed or prevented due to:
    - Temporary, scheduled, and unscheduled downtime of computer servers
    - Variations in server loads and processing times
    - Other data processing issues

NOTES:

- *The system does not provide continuous real-time monitoring.*
- *The LATITUDE Consult Communicator is non-sterile equipment. DO NOT STERILIZE. The wand must be contained in a sterile barrier to be used in the sterile field.*
- *The Communicator is designed for use only in the United States. Use of the Communicator in other countries is restricted.*

LATITUDE CONSULT COMMUNICATOR

A key component of the LATITUDE Consult system is the LATITUDE Consult Communicator. The Communicator is able to read data from an implanted Boston Scientific device, and then send that data to the LATITUDE Consult server through an analog telephone line (supports pulse or tone analog dialing modes) or through an Internet connection.

The Communicator is a portable device which can be used provided there is an accessible AC power outlet available. When the Communicator has completed collecting data from the implantable system, it can be unplugged without losing data. If necessary, you can reconnect the system in another location with an AC power outlet, and utilize either: 1) an accessible analog telephone line or 2) an Internet connection using the LATITUDE Wireless Internet Adapter.

The Communicator is designed to communicate with the secure server using:

1. An analog telephone line, such as those used by many fax machines. The Communicator may work on other telephone systems, such as Digital Subscriber Line (DSL) and Voice Over IP (VoIP), if those systems provide an analog interface for connecting the Communicator. If you have Digital Subscriber Line (DSL) Internet service provided through your telephone lines, you may need to install a DSL filter between the wall phone jack and the LATITUDE Communicator.

OR

2. An Internet connection. The LATITUDE Wireless Internet Adapter is available separately for this type of connection. Work with your System Administrator to ensure the LATITUDE Consult Communicator system and equipment is approved for use in your network enviroment.

Due to the size and portability of the Communicator, it is recommended that it be placed in an area that is secure.

Figure 1 and Table 1 identify the main parts of the Communicator.

Figure 1. Communicator (front and rear views)

Table 1. Communicator components

▼Callout	Description
A	Start Action button (round, blue) • Can be pressed to – start reading data from a patient's implanted device, send implanted device data to the server, or illuminate the LCD touch screen when it is dim (black).

Table 1. Communicator components (continued)

▼Callout	Description
B	Touch Screen • Gently touching the screen surface with a finger operates the touch screen. Respond to on-screen instructions or questions by touching the screen with a fingertip. Do not use tools or sharp objects as they can damage the touch screen. If the Communicator touch screen is dim* (black), simply touch any part of the screen to illuminate the screen. * After a period of non-use, the Communicator enters a power-saving mode and the LCD screen dims.
C	Indicator Light (oval) Press to illuminate the LCD touch screen when it is dim (black). The Indicator Light is lit or flashes when there are messages or instructions to follow: • White Light Blinking - Notification that clinician action is required: • Implanted device is out of range: While reading implanted device data, the indicator will blink if communication with the implanted device has been lost. If this occurs, move the wand closer to the implanted device, the flashing should stop, and reading should resume. • Reading of implanted device data is complete and ready to send. • No dial tone or other issue with analog telephone line when attempting to connect to the server. • Waiting for confirmation to erase implanted device data. • Solid White - Implanted device data has been successfully sent. Call Boston Scientific at 1-800-227-3422 to request a LATITUDE Consult review of the implanted device data. • Yellow Light - Notification that an error has occurred that requires clinician attention: • Blinking Yellow - Reading of implanted device data was unsuccessful. - or - Sending of implanted device data was unsuccessful. • Solid Yellow - Communicator error, call Boston Scientific at 1-800-227-3422.
D	Power Light (round, green) – Indicates the Communicator is connected to power.
E	Wand Cradle – Place the telemetry wand in the cradle when not in use.
F	Telemetry Wand The telemetry wand is used to read the data from the patient's implanted device. The telemetry wand should remain in the cradle when not in use.
G	Power Input jack – Connection for the Communicator's power supply.
H	Connection to a telephone or a fax machine (optional) The Communicator and a telephone/fax can share the same telephone wall jack. To do this, connect the telephone or fax machine to this jack on the back of the Communicator.
I	Connection to telephone wall jack (if using analog telephone line) Connect one end of the telephone cord to this jack and the other end to a telephone wall jack that supports an analog telephone line.

SETUP

The following items are included with the Communicator:

- Communicator unit with attached telemetry wand
- Communicator telephone cord
- Power supply
- Clinician User Manual

NOTE: *The LATITUDE Wireless Internet Adapter is required to set up an Internet connection. If the Communicator is connected through the Internet, an analog telephone line is not necessary.*

A 110 VAC outlet is needed to provide power to the Communicator.

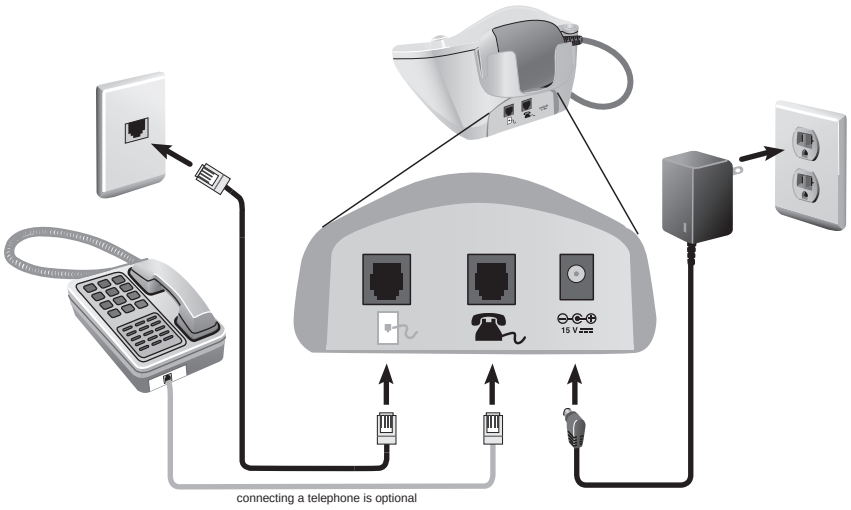
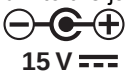


Figure 2. Connecting the Communicator

Powering up the Communicator

1. Insert the power supply cord into the jack labeled as shown below.



2. Plug the power supply into an electrical outlet that is easily accessible.
3. Make sure the green power light on the Communicator is On (see Figure 1 on page 6).
   - If the power light is not On, check that both ends of the power supply are plugged in firmly (steps 1 and 2).

INITIAL CONFIGURATION

Configuring the Communicator using an analog telephone line

NOTE: *This needs to be performed only once, unless the Communicator is connected to an analog telephone line with a different PBX[2] prefix or dialing method.*

1. From the Home screen, press the gear icon to display the Settings screen.
2. Press the phone icon to display the two phone line choices.
3. Press the Pulse (rotary dial) or Tone dialing icon to correspond to the dialing service of the analog telephone line that will be used for sending implanted device data.
4. Press OK to confirm and continue.
5. If the analog telephone line has a PBX prefix (the number to dial to get an outside line), press the <<< or >>> icons on the screen to display the desired prefix number. Press OK to confirm the selection.

   NOTE: *If there is no PBX prefix, just press OK when the default selection for No PBX displays.*

6. Press the Home icon to return to the Home screen. The settings are saved in the Communicator. The Communicator is now configured and ready for use.

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2. PBX - private branch exchange; a private telephone network used within an enterprise.

Configuring the Communicator using an Internet connection

NOTE: *The LATITUDE Wireless Internet Adapter is required to set up an Internet connection.*

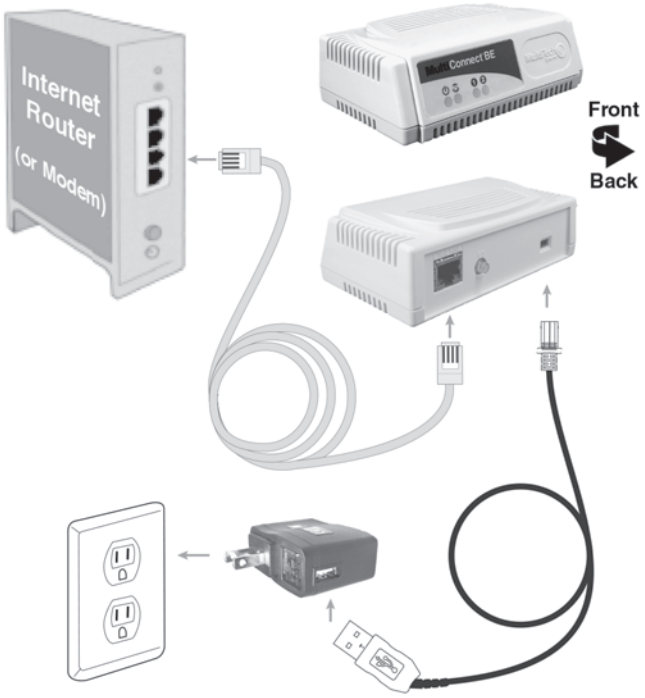

Figure 3. Connecting the Communicator

1. Position the Communicator within 100 Feet (30 meters) of the wireless internet adapter. Avoid physical obstructions between the Communicator and wireless internet adapter whenever possible.
2. Insert the micro end of the USB power cable (included with the wireless internet adapter) into the port on the back labeled “USB.”
3. Insert the standard (narrow) end of the USB power cable into the USB power adapter (included with the wireless internet adapter).
4. Plug the USB power adapter into an electrical outlet.
    - The power light on the front of the wireless internet adapter will light solid green.

Important: For the following steps, make sure you use the Ethernet cable provided with the wireless internet adapter and not the telephone cord provided with the Communicator.

5. Insert the Ethernet cable (included with the wireless internet adapter) into the port on the back of the wireless internet adapter labeled “ETHERNET.”
6. Plug the other end of the Ethernet cable into the Ethernet port of a modem, a router, or a Ethernet wall jack.
7. To begin pairing, press the button on the back of the wireless internet adapter. The indicator on front will flash green indicating pairing mode is active.
   - Pairing mode will end automatically after 60 minutes.

NOTE: *You can manually end pairing mode by pressing the button on the back of the* wireless internet adapter for 5 seconds.

8. From the Home screen of the Communicator, press the gear icon to display the Settings screen.
9. Press the upgrade icon on the Communicator to pair with the wireless internet adapter.
10. Press OK to confirm and continue.
11. Press the Home icon to return to the Home screen. The settings are saved in the Communicator. The Internet connection is now configured and ready for use.

READING DATA FROM THE PATIENT’S IMPLANTED DEVICE

NOTE: *Should it be necessary to stop reading the patient’s implanted device for any reason, simply move the wand away from the device. Then cancel the operation on the Communicator screen.*

1. Ensure the Communicator is powered On. See “Powering up the Communicator” on page 8 for details.
2. Have the patient sit or lie down in a comfortable position where the wand can reach and the Communicator screen can be viewed.
3. Place the telemetry wand over the patient’s implanted device and keep it in place until the reading is complete.
4. Press the patient icon on the Home screen to begin reading data from the patient’s implanted device.

NOTE: *If the wand moves away from the implanted device during the reading process, the Communicator displays a message to reposition the wand. Once communication is restored, reading of the implanted device data automatically continues.*

5. When the Communicator finishes reading the implanted device data, the Continue button >> Continue will be displayed. Place the wand back in the cradle and see the next section for Sending data.

NOTES:

- *If the reading of the implanted device data is unsuccessful and a retry is not successful, call Boston Scientific at 1-800-CARDIAC (227-3422).*
- *The Communicator can be unplugged and moved without loss of data.*
- *A patient's implanted device data remains on the Communicator until it is sent or erased. It must be either sent or erased before another patient's implanted device data can be read.*
- *To erase the implanted device data from the Communicator, press the Erase Data icon from the Home screen. Once it is erased, this data will not be recoverable from the Communicator.*

SENDING (TRANSMITTING) THE PATIENT'S IMPLANTED DEVICE DATA

1. Ensure the Communicator is powered On. See Figure 2 on page 8.
2. If using an analog telephone line:
   - Plug one end of the Communicator telephone cord into the jack labeled on the back of the Communicator.
   - Plug the other end of the Communicator telephone cord into the analog wall jack such as those used by many fax machines.
3. If using an Internet connection:
   - Ensure the Communicator is within 100 feet (30 meters) of the LATITUDE Wireless Internet Adapter.
4. If the data has been read from the patient's implanted device and the Communicator has remained powered On, press the Continue button to begin sending. Then, continue with step 6.
5. If the Communicator was unplugged after reading the implanted: device data and then powered back On, press the send icon on the Home screen to begin sending the data.

NOTE: *Do not disconnect the power cord, or disrupt the connection (analog telephone connection or Internet connection) until the data has been sent. If the Communicator is disconnected, simply reconnect it and retry sending the data. Implanted device data will not be lost.*

6. When the implanted device data has been sent, press the Done icon ☑.

NOTES:

- *If the sending of the implanted device data is unsuccessful and a retry is not successful, call Boston Scientific at 1-800-CARDIAC (227-3422).*
- *As soon as the patient's implanted device data has been successfully sent, that data is erased from the Communicator.*
- *If using an analog telephone line, the Communicator can share the same wall jack with a telephone or a fax machine. To continue to use the telephone or fax machine, plug its telephone cord into the jack with the telephone icon located on the back of the Communicator. The Communicator is designed to relinquish the line when a connected fax/telephone is used. If the Communicator does not relinquish the line (e.g. restore dial tone), unplug the Communicator from electrical power. The Communicator can be plugged back in after the line has been used.*
- *Occasionally, a software upgrade might be available for the Communicator unit, in which case the touch screen will display that a software upgrade is in progress. Do not disconnect the power cord, or disrupt the connection (analog telephone line connection or Internet connection) until the upgrade is complete. If the Communicator is disconnected, simply reconnect it and retry the upgrade.*

REVIEWING TRANSMITTED DEVICE DATA

Upon successful transmission of the implanted device data, to ensure review by Boston Scientific, call LATITUDE Consult Technical Services at 1-800-CARDIAC (227-3422) and request a LATITUDE Consult review of the implanted device data.

Upon request, optional reports[3] can be made available. The following is a list of the available optional reports:

- Transmission Report
- Quick Notes Report

[3] Adobe Acrobat Reader® program or compatible PDF viewer is required to view reports that are created in Portable Document Format (PDF).

- Combined Follow-up Report
- Presenting EGM Report
- Arrhythmia Logbook Report
- Event Detail / Episodes Report
- Device Settings Report

The implanted device data in each report is current as of the time the device was read, which can include up to 12 months of device/lead trend data and the most recent 72 hours of stored episodes.

The LATITUDE Consult system collects data that are protected health information. Designated Boston Scientific personnel have access to this data. In certain circumstances, Boston Scientific may contact clinician(s) regarding data received and/or Communicator status.

CARE AND MAINTENANCE

To ensure optimum performance of the Communicator and protect it from damage, follow these directions:

Prior to each use, perform a visual inspection and verify the following:

- Mechanical and functional integrity of the Communicator, cables, and power supply.
- Legibility and adherence of the Communicator labels.
- Appearance of Home screen after power is supplied to the Communicator. (The normal power-up process verifies that the Communicator has passed its internal checks and is ready for use.)

CAUTIONS:

- Do not drop or mishandle the Communicator in a manner that would cause damage.
- Avoid getting liquid on the unit other than cleaning it as recommended. Do not use abrasive cloth or solvents to clean the unit.
- Do not submerge the Communicator in liquid.
- Do not attempt to open the Communicator. The Communicator contains no user-accessible fuses or batteries.
- Use this unit as described in this clinician manual. Use only authorized parts and accessories. Do not attempt to modify or alter this unit or accessories. If the Communicator becomes damaged or malfunctions, contact Boston Scientific at 1-800-CARDIAC (227-3422).

- The Communicator is not waterproof or explosion-proof and cannot be sterilized. Do not use it in the presence of flammable gas mixtures including anesthetic mixture with air, oxygen, or nitrous oxide.

Cleaning the Communicator

When necessary, clean the Communicator housing and touch screen with a soft, clean, lint-free cloth moistened in water, isopropyl alcohol, or mild detergent. Note that the finish on some types of furniture could be affected as a result of continuous contact with rubber material such as the type used on the base of the Communicator.

CAUTIONS:

- Do not use other cleaning fluids. They may damage the Communicator touch screen. Never spray any cleaning fluid directly on the Communicator touch screen. Do not allow moisture to accumulate on or around the buttons.
- Avoid using any cleaning fluid near the electrical or phone jacks on the back of the Communicator.

Returning, Replacing, or Disposing of the Communicator

Do not dispose of the Communicator in the trash. If return or replacement is necessary, contact Boston Scientific at 1-800-CARDIAC (227-3422) for return and replacement instructions. The Communicator may contain encrypted personal health information.

Software Maintenance

If a software upgrade is available, it will be automatically installed on the Communicator immediately after sending implanted device data.

- If there is implanted device data on the unit from a previously un-sent transmission, the data will be sent automatically before the upgrade is installed.
- If this data is not to be sent, it must be erased before checking for upgrades by pressing the Erase data icon from the Home screen and following the prompts.

To manually check for software upgrades or test the setup and connection, perform the following:

1. Ensure that the Communicator is powered On. See Figure 2 on page 8.
2. If using an analog telephone line

- Plug one end of the Communicator telephone cord into the jack labeled on the back of the Communicator.
- Plug the other end of the Communicator telephone cord into the analog wall jack such as those used by many fax machines.

3. If using an Internet connection
   - Ensure the Communicator is within 100 feet (30 meters) of the LATITUDE Wireless Internet Adapter.

4. From the Home screen, press the gear icon to display the Settings screen.

5. Press the upgrade icon to connect to the server and follow the prompts.

6. When the upgrade is complete, press the Done icon.

NOTE: *Do not disconnect the power cord, or disrupt the connection (analog telephone connection or Internet connection) until the upgrade is complete. If the Communicator is disconnected, simply reconnect it and retry the upgrade.*

APPENDIX A: COMMUNICATOR TECHNICAL SPECIFICATIONS

Specifications

Table 1. LATITUDE Consult™ Communicator Specification

Specification	Value
Model:	6299
LCD Display:	Monochrome, 240 x 320 pixel, with touch screen control
Dimensions:	Length: 20.6 cm (8.1 in.) Width: 18.0 cm (7 in.) Height: 10.4 cm (4 in.)
Weight:	0.78 kg (1.7 lb.)
Power Source:	100-240 VAC, 47-63Hz
Power Supply	15.0 VDC, 1.2 A, 18.0 W, AC adapter, Globtek model GTM41061-1818-3.0 (included)
Supply Mains Isolation:	AC adapter plug
Protection against electrical shock:	Class II
Minimum Operational Loop Current:	20 mA
Expected Service Life:	15 years
Duty Cycle:	Continuous
Safety Classification of Ports:	RJ11 ports: TNV-3 circuit
Operating Temperature:	50° F to 95° F (10° C to 35° C)
Wand Temperature:	34° F [1° C] (typical) to 48° F [9° C] (maximum) above operating temperature
Storage and Transport Temperature:	-22° F to 158° F (-30° C to 70° C)
Operating Humidity:	25% to 75%
Storage and Transport Humidity:	25% to 95%
Storage and Transport Pressure:	50 to 106 kPa
Altitude Rating:	≤2,000 m
Protection Against Ingress of Water:	IPX0 Ordinary equipment

Table 1. LATITUDE Consult™ Communicator Specification (continued)

Specification	Value
Radio Frequency Transmitters:	
2.4 gHz Radio	
Operational Frequency:	2402.0 to 2480.0 MHz
Modulation Type:	Adaptive Frequency Hopping
Effective Radiated Power:	13.82 dBm (24 mW)
Implanted Device (PG) Radio	
Receive Bandwidth:	10kHz to 110 kHz
Receive Frequencies:	2.8 kHz / 56.9 kHz / 102.4 kHz
Transmit Frequency:	57.0 kHz +/- 11.4 kHz
Modulation Transmit Type:	OOK (On-Off keying)
Effective Radiated Power:	≤ 5.32 µW (@ 300 m)
Phone Line:	Analog line with Pulse or Tone dialing

Software

The software included in this product contains copyrighted software that is licensed under the GNU General Public License (GPL). Under the terms of the GPL as published by the Free Software Foundation, the complete Corresponding Source code may be obtained from us for a period of three years after our shipment of this product. The software is based in part of the work of the FreeType Team.

APPENDIX B: COMMUNICATOR STANDARDS INFORMATION

This appendix provides LATITUDE Consult™ Communicator (Model 6299) instructions for use information that is required by applicable standards and regulations.

Safety and Standards Compliance

- Changes or modifications not expressly approved by Boston Scientific could void the user's authority to operate this equipment.
- The use of accessories and cables other than those specified may result in increased emissions or decreased immunity of the Communicator. Using accessories and cables supplied with the Communicator in other medical equipment and systems may result in increased emissions or decreased immunity of the other medical equipment or systems.
- Do not insert anything other than a telephone connector into the telephone jacks on the back of the Communicator. There can be voltage on the electrical contacts in the connector, and there is potential to receive a shock.

  CAUTION: Once the Communicator is connected to an active telephone wall jack, the second telephone jack on the back of the Communicator becomes a live jack. Avoid contact inside this telephone jack if it is not being used.
- Accessory equipment connected to the Communicator must be certified according to the respective standards. Anyone connecting such accessories to the Communicator may be configuring a medical system and is responsible to ensure that the system complies with the requirements of IEC/EN 60601-1, Clause 16 for medical electrical systems.
- A plug and jack used to connect this equipment to the premises wiring and telephone network must comply with the applicable FCC Part 68 rules and requirements adopted by the ACTA. A compliant telephone cord and modular plug is provided with this product. It is designed to be connected to a compatible modular jack that is also compliant. See installation instructions for details.
- Other wireless communication equipment could interfere with the Communicator even if the other equipment complies with CISPR (Special International Committee on Radio Interference) emission requirements.
- The telephone company may make changes in its facilities, equipment, operations or procedures that could affect the operation of the

equipment. If this happens the telephone company will provide advance notice in order to make necessary modifications to maintain uninterrupted service.

- If the Communicator causes harm to the telephone network, the telephone company will notify you in advance that temporary discontinuance of service may be required. But if advance notice isn't practical, the telephone company will notify the customer as soon as possible. Also, you will be advised of your right to file a complaint with the FCC if you believe it is necessary.
- If trouble is experienced with the Communicator, for repair or warranty information, please contact Boston Scientific at 1-800-227-3422. If the equipment is causing harm to the telephone network, the telephone company may request that you disconnect the equipment until the problem is resolved.
- If the facility has specially wired alarm equipment connected to the telephone line, ensure the installation of the Communicator does not disable the alarm equipment. If there are questions about what will disable alarm equipment, consult the telephone company or a qualified installer.
- Do not use the Communicator adjacent to or stacked with other equipment. If it is necessary to use the Communicator adjacent to or stacked with other equipment, please contact Boston Scientific at 1-800-227-3422 to verify normal operation.
- This device complies with Title 47, Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- This equipment complies with Part 68 of the FCC rules and the requirements adopted by the ACTA. On the [insert location of the label] of this equipment is a label that contains, among other information, a product identifier in the format US:AAAEQ##TXXXX. If requested, this number must be provided to the telephone company. The Ringer Equivalence Number (REN) for this product is part of the product identifier. The digits represented by ## are the REN. The REN is used to determine the number of devices that may be connected to a telephone line. Excessive RENs on a telephone line may result in the devices not ringing in response to an incoming call. In most but not all areas, the sum of RENs should not exceed five (5.0). To be certain of the number of devices that may be connected to a line, as determined by the total RENs, contact the local telephone company. The REN for this product is 0.0.
- This equipment has been tested and found to comply with applicable safety portions of the AAMI ES 60601-1:2005, CAN/CSA-C22.2 NO. 60601-1:08 and IEC 60601-1:2005 standards.

- This equipment has been tested and found to comply with the following EMC standards: IEC 60601-1-2:2007.
- The LATITUDE Consult Communicator does not provide any performance which is essential to maintain freedom from unacceptable risk as defined by IEC 60601-1:2005.
- The LATITUDE Consult Communicator has the ability to:
  - Communicate with a Boston Scientific implanted device
  - Communicate implanted device data to the LATITUDE Consult System
  - Receive configuration updates from the LATITUDE Consult System

Electromagnetic Emissions and Immunity

Table 1. Guidance and manufacturer's declaration—electromagnetic emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Model 6299 LATITUDE Consult™ Communicator is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 6299 LATITUDE Consult Communicator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment—guidance**
RF emissions CISPR 11	Group 1	The Model 6299 LATITUDE Consult Communicator uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Model 6299 LATITUDE Consult Communicator is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 2. Guidance and manufacturer's declaration—electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 6299 LATITUDE Consult™ Communicator is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 6299 LATITUDE Consult Communicator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the LATITUDE Consult Communicator requires continued operation during power mains interruptions, it is recommended that the LATITUDE Consult Communicator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 3. Guidance and manufacturer's declaration—electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 6299 LATITUDE Consult™ Communicator is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 6299 LATITUDE Consult Communicator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the LATITUDE Consult Communicator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distances**:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 10 Vrms in ISM and amateur radio bands[c] between 150 kHz and 80 MHz	$d = 1.7 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m (80 MHz to 1000 MHz) 17 V/m (380 MHz to 390 MHz) 14 V/m (430 MHz to 470 MHz) 24 V/m (800 MHz to 960 MHz) 3 V/m (1 GHz to 2.7 GHz) 24 V/m (1.7 GHz to 1.99 GHz) 24 V/m (2.4 GHz to 2.57 GHz) 8 V/m (5.1 GHz to 5.8 GHz)	d = 0.5 √P (80 MHz to 1000 MHz) d = 0.29 √P (380 MHz to 390 MHz) d = 0.36 √P (430 MHz to 470 MHz) d = 0.21 √P (800 MHz to 960 MHz) d = 1.7 √P (1 GHz to 2.7 GHz) d = 0.21 √P (1.7 GHz to 1.99 GHz) d = 0.21 √P (2.4 GHz to 2.57 GHz) d = 0.63 √P (5.1 GHz to 5.8 GHz)

Table 3. Guidance and manufacturer's declaration—electromagnetic immunity (continued)

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 6299 LATITUDE Consult™ Communicator is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 6299 LATITUDE Consult Communicator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**
			where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:
NOTE 1 At 80MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. NOTE 3 The recommended separation distance is calculated using the formula $d = [5/E_1] \sqrt{P}$.			

Table 3. Guidance and manufacturer's declaration—electromagnetic immunity (continued)

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model 6299 LATITUDE Consult™ Communicator is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 6299 LATITUDE Consult Communicator should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment—guidance**

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 6299 LATITUDE Consult Communicator is used exceeds the applicable RF compliance level above, the Model 6299 LATITUDE Consult Communicator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Model 6498 LATITUDE Communicator.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c. The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 150 kHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Table 4. Recommended separation distances between portable and mobile RF communications equipment and the LATITUDE Consult™ Communicator

Recommended separation distances between portable and mobile RF communications equipment and the LATITUDE Consult Communicator

The LATITUDE Consult Communicator is intended for use in an electromagnetic environment in which radiated RFdisturbances are controlled. The customer or the user of the LATITUDE Consult Communicator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the LATITUDE Consult Communicator as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (meters)**						
	150 kHz to 80 MHz $d = 1.7\sqrt{P}$	80 MHz to 1000 MHz $d = 0.5\sqrt{P}$	380 MHz to 390 MHz $d = 0.29\sqrt{P}$	430 MHz to 470 MHz $d = 0.36\sqrt{P}$	800 - 960 MHz 1.7 - 1.99 GHz 2.4 - 2.57 GHz $d = 0.21\sqrt{P}$	1 GHz to 2.7 GHz $d = 1.7\sqrt{P}$	5.1 GHz to 5.8 GHz $d = 0.63\sqrt{P}$
0.01	0.17	0.050	0.029	0.36	0.021	0.17	0.063
0.1	0.54	0.16	0.092	0.11	0.066	0.54	0.20
1	1.7	0.50	0.29	0.36	0.21	1.7	0.63
10	5.4	1.6	0.92	1.1	0.66	5.4	2.0
100	17	5.0	2.9	3.6	2.1	17	6.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE 3 The recommended separation distance is calculated using the formula $d = [5/E1]\sqrt{P}$.

APPENDIX C: SYMBOLS ON PACKAGING, DEVICE, AND ACCESSORIES

This appendix provides explanations of the symbols used on the LATITUDE Consult™ Communicator, its packaging, and its accessories.

Table 1. Symbols on Packaging, Device, and Accessories

Symbol	Meaning
	Do not use if package is damaged
	Date of manufacture
	Follow instructions for use
	Manufacturer
	MR Unsafe
	Non-ionizing radiation
	TUV (Technischer Überwachungs-Verein) mark
	Type B applied part (telemetry wand)
	WEEE symbol (waste of electrical and electronic equipment) Do not throw in the trash.
	Analog line connection jack on Communicator
	Telephone/fax connection jack on Communicator

Table 1. Symbols on Packaging, Device, and Accessories (continued)

Symbol	Meaning
	Power input jack on Communicator
	Direct Current symbol on Communicator
Symbols on power supply:	
	Refer to Instructions
	Standard of the electronics industry of the People's Republic of China
	Indoor use only
	EISA Energy Star tier 2
	Intertek S mark (Europe)
	Intertek ETL mark (North America)
	China Quality Certification (CQC) and Japan Product Safety Electric Appliance and Materials mark (PSE)
	Do not dispose of in trash
	Keep dry

Table 1. Symbols on Packaging, Device, and Accessories (continued)

Symbol	Meaning
	Class II electrical device
	CE mark of conformity
	Voluntary Control Council for Interference by Information Technology Equipment (Japan)
	DC power jack
Symbols on shipping carton:	
	Temperature symbol on outer shipping carton
	Humidity symbol on outer shipping carton
	Pressure symbol on outer shipping carton

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